

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: McDonald et al.	Examiner: OLSON, Eric
Serial No: 10/613,788	Art Unit: 1623
Filed: July 3, 2003	Attorney Ref. No: 8105-009-US-CON
Title: METHOD OF LONG TERM TREATMENT OF GRAFT-VERSUS-HOST DISEASE USING TOPICAL ACTIVE CORTICOSTEROIDS	

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SUPPLEMENTAL REPLY UNDER 37 C.F.R. § 1.111

Dear Sir:

In response to the Office Action mailed September 27, 2006, applicant submits this Supplemental Reply in conformity with 37 C.F.R. § 1.111. This response incorporates suggestions discussed via telephone with the Examiner.

Applicant respectfully requests this Supplemental Reply be reviewed in conjunction with the Request for Continued Examination filed on February 27, 2007.

Specifically, this Supplemental Reply contains a Declaration under 37 C.F.R. §1.132, describing the state of the art in corticosteroid administration and then-current belief regarding the potential disastrous effects from administration beyond 30 days. The Declaration is made by Dr. George McDonald, who is both the named inventor of the present application and author of the current prior art of record (McDonald et al.). As such, he is the ideal individual to establish and explicitly make clear the rationale behind ceasing the study described in McDonald et al. before 30 days.

This Declaration evidences the lack of motivation of one skilled in the art to carry out a corticosteroid-based therapy for a term in excess of 30 days. As discussed with Examiner, the reason the prior art of record ceased their study before 30 days was fear of patient safety based on the knowledge at the time of the negative effects from corticosteroid administration lasting more than 30 days. This is contrary to Examiner's allegations that it would have been obvious to one skilled in the art to extend beclomethasone dipropionate therapy beyond 30 days and that one skilled in the art "would reasonably extend the therapy to the longer period from 30 days or less to 56 days if such treatment is still required after 30 days from the beginning of treatment." *Office Action mailed 9/27/06, p.4.* As depicted in the Declaration, one skilled in the art would not have been motivated given the profoundly negative effects known in the field from extending corticosteroid therapy beyond 30 days.


As this Reply is submitted before the Examiner has considered the previously submitted Request, no fee is believed to be required.

Applicant submits that the case is now in condition for allowance. Early notification of such action is earnestly solicited. If there are any questions or comments, Applicant's attorney may be reached at the telephone number state below.

Respectfully submitted,

Dated: March 23, 2007

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